

## REMARKS

### Rejection of Claims and Traversal Thereof

In the January 12, 2004 Office Action,

(1) claims 2, 3, 15-18, 20, 21, 24-26, 28 and 31 were rejected under 35 U.S.C. §112, second paragraph;

(2) claims 1, 4, 9-12 and 15 were rejected under 35 U.S.C. §102(b) as being anticipated by Robledo (Robledo et al. (1999) Nucleotide Sequence Variability in the Nontranscribed Spacer of the rRNA Locus in the Oyster Parasite *Perkinsus marinus*. J. Parasitol. 85:650-656)(hereinafter Robledo 1);

(3) claims 1, 4, 9-11, 13, 15 were rejected under U.S.C. §102(b) as being anticipated by Marsh (Marsh, et al. (1995) A semiquantitative PCR Assay for Assessing *Perkinsus marinus* Infections in the Eastern Oyster, *Crassostrea Virginica*, J. Parasitol. 81(14); 577-583)(hereinafter Marsh);

(4) claims 1, 2 and 4, 9-18 were rejected under 35 U.S.C. §102(a) as being anticipated by Robledo (Robledo, J.A., C.A. Coss and G.R. Vasta (2000) Characterization of the Ribosomal RNA Locus of *Perkinsus atlanticus* and Development of a Polymerase Chain Reaction-Based Diagnostic Assay. J. Parasitol. 86:972-978) (hereinafter Robledo 2) and claims 1, 4, 9 and 15 were rejected under 35 U.S.C. §102(a) as being anticipated by Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) (hereinafter Robledo 3);

(5) claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 1 in view of Stokes (Stokes, N.A. and Burrenson, E.M. 1995. A sensitive and Specific DNA Probe for the Oyster Pathogen *Haplosporidium Nelsoni*. J. Euk. Microbiol. 42: 350-357);

(6) claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 2 in view of Stokes;

(7) claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 1 or Marsh (Marsh, A.G., J.D. Gauthier, G.R. Vasta. 1995. A semiquantitative PCR assay for assessing

*Perkinsus marinus* infections in the eastern oyster, *Crassostrea virginica*. *J. Parasitol.*, 81: 577-583) in view of the Stratagene Catalog (1988);

(8) claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 2 in view of the Stratagene Catalog (1988);

(9) claims 2, 9-11, 13 and 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 3 in view of the Marsh;

(10) claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 3 in view of Marsh and in further view of the Stratagene Catalog (1988); and

(11) claims 21-30 were rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-17 of prior patent U.S. Patent No. 6,326,485.

These rejections are traversed and reconsideration of the patentability of the pending claims is requested in light of the following remarks.

#### **Inventorship and Priority of Claims**

Claims 1-3 as amended recite oligonucleotides and method of making such oligonucleotides that hybridize to SEQ ID NO: 18 under stringent annealing conditions for species-specific detection. These oligonucleotides are not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference), and Robledo 2 and 3 are removed as prior art by newly filed Declaration by Dr. Vasta. (Claims have a priority date of 2001 and inventors include: Coss, Robledo and Vasta).

Claims 4-8 are cancelled herein.

Claims 9-13 recite oligonucleotides that hybridizes to the SEQ ID NO: 18 under stringent annealing conditions for species-specific detection and are not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference), and Robledo 2 and 3 are removed as prior art by enclosed Declaration by Dr. Vasta. (Claims have a priority date of 2001 and inventors include: Coss, Robledo and Vasta).

Claim 14 is cancelled herein.

Claim 15 recites that the oligonucleotide of claim 1 is complementary to at least a part of SEQ ID NO. 18 and this oligonucleotide is not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference), and Robledo 2 and 3 are removed as prior art by enclosed Declaration by Dr. Vasta. (Claim has a priority date of 2001 and inventors include: Coss, Robledo and Vasta).

Claim 16-18 recites methods of isolating NTS SEQ ID NO: 18 for use in synthesizing oligonucleotides that hybridizes to the SEQ ID NO: 18 under stringent annealing conditions for species-specific detection. The claimed subject matter is not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference), and Robledo 2 and 3 are removed as prior art by enclosed Declaration by Dr. Vasta. (Claims have a priority date of 2001 and inventors include: Coss, Robledo and Vasta).

Claim 19 has been cancelled.

Claim 20 as amended recite a kit including oligonucleotides SEQ ID NOs. 8, and 9 which are not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference), Robledo 2 and 3 are removed as prior art by enclosed Declaration by Dr. Vasta. (Claim has a priority date of 1/30/2001 and inventors include: Coss, Robledo and Vasta).

Claims 21-26 as written recite SEQ ID NOs. 1, 2, 3, 12, 13, 14, 15 and 19. SEQ ID NOs 1, 2 and 3 are disclosed in parent application filed on July 25, 1997, sequences 12, 13, 14, 15 and 19 have a priority date of 1/30/2001. None of the cited reference disclosed oligonucleotide sequences. (Claims have a priority date of 1/30/2001 and inventors include: Coss, Robledo, Vasta, Wright and Marsh).

Claim 27 (Cancelled)

Claim 28 as written recites NTS having a sequence of SEQ ID NO: 24 or 25 that were disclosed in parent application filed on July 25, 1997. (Claims have a priority date of parent application and inventors include: Coss, Robledo, Vasta, Wright and Marsh).

Claims 29-30 (Cancelled)

Claim 31 as written recites SEQ ID NOs. 12, 13, 14, 15 and 19 and these sequences are not disclosed in Robledo 1 (AX Reference), Marsh (AP Reference), Robledo 2 or Robledo 3. (Claim has a priority date of 1/30/2001 and inventors include: Coss, Robledo, Vasta, Wright and Marsh).

Claim 32 as written recites the oligonucleotides disclosed in parent application and thus has a priority date of the parent application. (The inventors include: Coss, Robledo, Vasta, Wright and Marsh).

**Rejection under 35 U.S.C. §112, Second Paragraph**

(1) Claims 2, 3, 15-18, 20, 21, 24-26, 28 and 31 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claims 2, 3, 15-18, 20, 21, 24-26, 28 thereby obviating all rejections under §112, second paragraph.

**Rejection under 35 U.S.C. §102(b)**

(2). Claims 1, 4, 9-12 and 15 were rejected under 35 U.S.C. §102(b) as being anticipated by Robledo (Robledo et al. (1999) Nucleotide Sequence Variability in the Nontranscribed Spacer of the rRNA Locus in the Oyster Parasite *Perkinsus marinus*. *J. Parasitol.* 85:650-656)(hereinafter Robledo 1). Applicants traverse this rejection.

Applicants have amended independent claim 1, and claims depending therefrom to recite a NTS consisting of SEQ ID NO: 18, which is the nucleotide sequence of the NTS of *P. atlanticus* and the oligonucleotides hybridizes to this NTS under stringent annealing conditions for species-specific detection. The Robledo 1 reference does not disclose oligonucleotides that hybridize to at least a part of SEQ ID NO. 18, wherein the hybridization conditions provide for species-specific detection. The specification of the present application expressly defines the phrases "species-specific" and "stringent annealing conditions" at the bottom of page 17 and top of page 18. Such express definitions provide a framework for determining whether or not the cited reference in fact disclose or suggest oligonucleotides

that hybridize to the NTS SEQ ID NO: 18 for species-specific detection within the meaning of the present application.

The following analysis clearly shows that Robledo 1 does not teach or suggest the presently claimed invention. The term "species-specific" is clearly defined in the present specification, as meaning the following:

"Species-specific' means detection, amplification or oligonucleotide hybridization in a species of organism or a group of related species without substantial detection, amplification or oligonucleotide hybridization in other species of the same genus or species of a different genus."

Further the hybridization occurs under stringent annealing conditions as defined in the present invention. Specifically, the conditions are defined as "in those conditions the specificity, efficiency and fidelity of the PCR amplification will generate one and only one amplification product that is the intended target sequence."

Clearly, the Robledo 1 reference does not "identically disclosed or described" the presently claimed invention as required of an anticipatory reference applied under section 102. (See *In re Felton*, 179 USPQ 295 (CCPA 1973)). According to the Office, "The nucleic acid of Robledo shares extensive sequence identity with SEQ ID NO: 18 and have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of SEQ ID NO: 18." Applicants vigorously disagree because the oligonucleotides described in Robledo 1 bind to the NTS of *P. marinus* and as stated in the present application at page 32, the NTS of *P. marinus* has only 62% identity to that of SEQ ID NO: 18. Thus, there is no possibility that oligonucleotide described in Robledo 1 could or would bind with species-specificity to SEQ ID NO: 18 under stringent annealing conditions.

Claim 12 recites the use of primers SEQ ID NOs: 8 and 9 that hybridize to only SEQ ID NO: 18 as described at page 32, the last paragraph, wherein the specificity of these primers was discussed and the results show that the primers did not amplify *P. marinus* or *Perkinsus sp.*

Thus, Robledo 1 does not anticipate the presently claimed invention because it does not disclose each and every element of the presently claimed invention. Applicants request the rejection under 35 U.S.C. §102(b) be withdrawn.

(3) Claims 1, 4, 9-11, 13, 15 were rejected under U.S.C. §102(b) as being anticipated by Marsh (Marsh, et al. (1995) A semiquantitative PCR Assay for Assessing *Perkinsus Marinus* Infections in the Eastern Oyster, *Crassostrea Virginica*, *J. Parasitol.* 81(14); 577-583)(hereinafter Marsh);

Applicants have amended independent claim 1, and claims depending therefrom to recite a NTS consisting of SEQ ID NO: 18, which is the nucleotide sequence of the NTS of *P. atlanticus* and the oligonucleotides hybridizes to the NTS under stringent annealing conditions for species-specific detection. The Marsh reference does not disclose oligonucleotides that hybridize to at least a part of SEQ ID NO. 18, wherein the hybridization conditions provide for species-specific detection.

Thus, Marsh does not anticipate the presently claimed invention because it does not disclose each and every element of the presently claimed invention. The Marsh reference does not meet the statutory requirements of an anticipating reference because each and every element of the claimed invention is not found in the cited reference. Applicants request the rejection under 35 U.S.C. §102(b) be withdrawn.

#### **Rejection under 35 U.S.C. §102(a)**

(4). Claims 1, 2 and 4, 9-18 were rejected under 35 U.S.C. §102(a) as being anticipated by Robledo (Robledo, J.A., C.A. Coss and G.R. Vasta (2000) Characterization of the Ribosomal RNA Locus of *Perkinsus atlanticus* and Development of a Polymerase Chain Reaction-Based Diagnostic Assay. *J. Parasitol.* 86:972-978) (hereinafter Robledo 2) and claims 1, 4, 9 and 15 were rejected under 35 U.S.C. §102(a) as being anticipated by Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) (hereinafter Robledo 3). Applicants traverse these rejections.

Initially, it should be noted that 35 U.S.C. §116 permits multiple inventive entities in one application and that inventors may apply for a patent jointly even though each did not make a contribution to the subject matter of every claim of the patent. Further Rule 1.45 provides for different inventive entities to join in an application by stating that:

"[I]f multiple inventors are named in an application, each named inventor must have made a contribution, individually or jointly, to the subject matter of at least one claim of the application and the application will be considered to be a joint application under 35 U.S.C. §116."

Applicants have included herewith a Declaration under 35 USC §132 (Appendix A) executed by Dr. Vasta attesting to the fact that Vasta, Robledo and Coss are co-inventors of the subject matter recited in claims 1-3, 9-13, 15-18 and 20 and also co-authors of the cited publications (Robledo 2 and 3) that describe their own work. Thus, the authorship of the publications and the inventorship of the subject matter recited in claims 1-3, 9-13, 15-18 and 20 is the same inventive entity. The declaration further states that the subject matter recited in claims 21-26, 28 and 31-32 is the inventorship of the inventive entity of Vasta, Robledo, Coss, Marsh and Wright. The Declaration still further states that Adam Marsh and Anita Wright were not in the lab during the research for and writing of the Robledo 2 and 3 references and thus are not co-inventors of the subject matter recited in claims 1-3, 9-13, 15-18 and 20. However, Marsh and Wright are properly included as joint applicants of the present application because they are co-inventors along with Vasta, Coss and Robledo of the subject matter recited in claims 21-26, 28 and 31-32.

According to the Board of Patent Appeal and Interferences (BPAI) in *In re Magner*<sup>1</sup>, the enclosed affidavit is sufficient to explain the relation of the publication authored by less inventors than that named in the presently filed application. The presently enclosed affidavit provides competent evidence to convince the Office as to why the Robledo 2 publication names only three inventors and why the additional inventors were named as co-inventors on the application. Further, there is no reason to doubt the statement of the affiant as the enclosed affidavit provides no benefit to the affiant. The enclosed affidavit is sufficient to remove the cited publications as competent references under 35 USC 102(a).

#### **Rejection under 35 U.S.C. §103(a)**

(5) . Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 1 in view of Stokes. Applicants traverse this rejection.

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<sup>1</sup> *In re Magner, Long, Ellis and Grinstead*, 133 USPQ 404 (BPAI 1962)

The Office is relying on the teachings of the primary reference for teaching isolated nucleic acids comprising the NTS region of the *Perkinsus marinus*. Stokes is cited for teaching labeling of nucleic acid probes. However, applicants have amended claim 1 and all claims depending therefrom to recite that the oligonucleotides hybridize to SEQ ID NO: 18, which is the nucleotide sequence of the NTS of rRNA of *P. atlanticus* and these oligonucleotides hybridize under stringent annealing conditions that provide for species-specific detection.

Applicants submit that neither Robledo 1 alone or in combination with Stokes render applicants' claimed invention *prima facie* obvious.

According to MPEP 706.02(j):

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir 1991)."

Claim 13 relates to detectably labeling the oligonucleotides of claim 1. Applicants submit that there is no teaching or suggestion in either reference or the combination thereof to generate or use oligonucleotides that hybridize to SEQ ID NO: 18 under stringent annealing conditions to provide for species-specific detection in an assay.

For a *prima facie* case of obviousness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. See *In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976). The mere fact that the prior art could be modified as proposed by the Office is not sufficient to establish a *prima facie* case of obviousness. See *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

Clearly, even if the references are combined, each and every element contained in the present claim is not disclosed, taught or suggested. Specifically Robledo 1 does not disclose or suggest oligonucleotides that



have the ability to hybridize with SEQ ID NO. 18 under stringent annealing conditions that provide for species-specific detection of *P. atlanticus* in an assay, and as such, the combination is insufficient to establish obviousness. Applicants request that the rejection of claim 13 under 35 USC §103(a) be withdrawn.

(6) Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 2 in view of Stokes. Applicants traverse this rejection.

The Office is relying on the teachings of the primary reference for teaching isolated nucleic acids comprising the NTS region of the *Perkinsus atlanticus*. Stokes is cited for teaching labeling of nucleic acid probes. However, by virtue of the concurrently submitted Declaration by Dr. Vasta, the Robledo 2 reference is not competent prior art to defeat the patentability of claim 13 and thus the combination therefore fails as a tenable basis for rejecting claim 13 because all elements of applicants' claimed invention are not disclosed, taught or suggested.

(7). Claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 1 or Marsh in view of the Stratagene Catalog (1988). Applicants traverse these rejections.

The Office is relying on the teachings of the primary references Robledo 1 or Marsh for teaching isolated nucleic acids comprising the NTS region of the *Perkinsus marinus*. The Stratagene Catalog is cited for teaching the general concept of kits for performing nucleic acid hybridization methods. However, applicants have amended claim 3 and all claims depending therefrom to recite a kit that includes primers that hybridize to SEQ ID NO: 18 under stringent annealing conditions to provide a species-specific detection to assay *P. atlanticus*. Applicants submit that there is no teaching or suggestion in either reference or the combination thereof to use oligonucleotides that hybridize to SEQ ID NO: 18 under stringent annealing condition to provide a species-specific detection of *P. atlanticus* in an assay kit. Thus, even if the references are combined, each and every element contained in the claims is not disclosed, and thus the combination is insufficient to establish obviousness.

Claim 31 as amended recites a kit for determining the identity of species of a microorganism of the genus *Perkinsus*, comprising a container having outwardly directed PCR primer pairs to a non-transcribed spacer sequence flanked by rRNA genes, said primer pairs, having a nucleic acid sequence selected from

the group consisting of sequences of SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and SEQ ID NO. 19 (as shown in Figure 20 and Figure 21 of the present specification). These sequences are not disclosed in Robledo 1 (AX Reference) or Marsh (AP Reference) alone or in combination with the Stratagene Catalog. Thus, that which is not shown or unknown cannot be obvious. Accordingly, applicants request that the rejection of claims 3 and 31 under 35 USC §103(a) be withdrawn.

(8) Claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 2 in view of the Stratagene Catalog (1988). Applicants traverse this rejection.

The Office is relying on the teachings of the primary references Robledo 2 for teaching isolated nucleic acids that hybridize to the NTS region of the *Perkinsus atlanticus*. The Stratagene Catalog is cited for teaching the general concept of kits for performing nucleic acid hybridization methods. However, by virtue of the concurrently submitted Declaration by Dr. Vasta and Dr. Robledo, the Robledo 2 reference is not competent prior art to defeat the patentability of the subject matter of claim 3.

Claim 31 as amended recites a kits for determining the identity of species of a microorganism of the genus *Perkinsus*, comprising a container having outwardly directed PCR primer pairs to a non-transcribed spacer sequence flanked by rRNA genes, said primer pairs, having a nucleic acid sequence selected from the group consisting of sequences of SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and SEQ ID NO. 19 (as shown in Figure 20 and Figure 21 of the present specification). These sequences are not disclosed in Robledo 2 alone or in combination with the Stratagene Catalog. Thus, that which is not shown or unknown cannot be obvious. Accordingly, applicants request that the rejection of claims 3 and 31 under 35 USC §103(a) be withdrawn.

(9) Claims 2, 9-11, 13 and 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 3 in view of the Marsh. Applicants traverse this rejection.

The Office is relying on the teachings of the primary references Robledo 3 for teaching isolated nucleic acids comprising the NTS region of the *Perkinsus atlanticus*. Marsh is cited for teaching labeling of the NTS sequences so that they may be used for probes. However, by virtue of the concurrently submitted Declaration by Dr. Vasta, the Robledo 3 reference cannot be considered competent prior art to defeat the patentability of the subject matter recited in claims 2, 9-11, 13 and 16-18. Further, Marsh is completely

silent regarding the NTS of *P. atlanticus*, and thus, the combination fails as a tenable basis for rejecting claims 2, 9-11, 13 and 16-18 because all elements of applicants' claimed invention are not disclosed, taught or suggested. Withdrawal of rejection under 35 USC 103(a) is requested.

(10) Claims 3 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robledo 3 in view of Marsh and in further view of the Stratagene Catalog (1988). Applicants traverse this rejection.

The Office is relying on the teachings of the combination of Robledo 3 and Marsh as above and the Stratagene Catalog for teaching the use of a kit. However, by virtue of the concurrently submitted Declaration by Dr. Vasta, the Robledo 3 reference is not competent prior art to defeat the patentability of the subject matter recited in claim 3.

Claim 31 as amended recites a kits for determining the identity of species of a microorganism of the genus *Perkinsus*, comprising a container having outwardly directed PCR primer pairs to a non-transcribed spacer sequence flanked by rRNA genes, said primer pairs, having a nucleic acid sequence selected from the group consisting of sequences of SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and SEQ ID NO. 19 (as shown in Figure 20 and Figure 21 of the present specification). These sequences are not disclosed in Robledo 3 or Marsh alone or in combination with the Stratagene Catalog. Thus, that which is not shown or unknown cannot be obvious. Accordingly, applicants request that the rejection of claims 3 and 31 under 35 USC §103(a) be withdrawn.

(11) Claims 21-30 were rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-17 of prior patent U.S. Patent No. 6,326,485. Applicants vigorously disagree.

Under 35 U.S.C. §101, a person is entitled to a patent, unless the Office can establish a *prima facie* case of double patenting. The Office must show that the claims in the present application are **identical** to the subject matter recited in Chang '858. Thus, the Office must show that the **same invention is being claimed twice.**

It is well settled in the law that a double patenting determination involves two inquiries. (*See In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993)). First, is the same invention claimed twice? *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1843 (Fed. Cir. 1992). This inquiry

hinges upon the scope of the claims in question. *In re Vogel*, 164 USPQ 619 (CCPA 1970). The Court in *In re Vogel*, held that:

"By the same invention we mean identical subject matter. Thus the invention defined by a claim reciting 'halogen' is not the same as that defined by the claim reciting 'chlorine,' because the former is broader than the latter."

Thus, if the claimed inventions are not **identical in scope** a rejection under U.S.C. §101 is not proper.

With regards to the first inquiry, claim 21, as amended herein recites an oligonucleotide with the following elements (limitations):

21. An oligonucleotide which hybridizes to a non-transcribed spacer sequence between rRNA genes of an organism of the genus *Perkinsus* being assayed, wherein said organism of genus *Perkinsus* contains a nucleotide base sequence selected from the group consisting of the sequences of SEQ ID NOs. 1, 2, and 3, wherein the oligonucleotides are selected from SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and SEQ ID NO. 19.

The oligonucleotides are clearly defined as having sequences SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 or SEQ ID NO. 19. A comparison of claim 21 (present application) and independent claims 1, 11 and 15 of U.S. Patent No. 6,326,485 shows that the **claims are not identical in scope.** As stated above, if one claimed invention has a broader scope than the other, a rejection under U.S.C. §101 is not proper.

Moreover, double patenting must be determined by an analysis of the claims as a whole. *Carman Indus., Inc. v. Wahl*, 220 USPQ 481 (Fed. Cir. 1983). Independent claims 21 and 28, of the present invention include the additional elements that are not recited in any of the claims in U.S. Patent No. 6,326,485. For example, claim 21 recites oligonucleotides having nucleotide sequences selected from SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and SEQ ID NO. 19. Claim 28 recites specific sequences for the NTS, that being SEQ ID NO: 24 or 25. Thus, the claims of U.S. Patent No. 6,326,485 do not include the third element as recited the present claims 21 and 28, and as such, the subject matter of these claims are not patented in U.S. U.S. Patent No. 6,326,485. It is evident that the claims of the present application and those of U.S. Patent No. 6,326,485 are not co-extensive in scope. If one claimed invention has a broader scope than the other, then the same invention is not claimed twice and the second inquiry must be made as to whether the claims of the application define an obvious variation of the other

patent claim which may be overcome by filing a terminal disclaimer. Applicants have already filed a terminal disclaimer in the present invention, so this inquiry is a moot point.

Applicants submit that the Office has failed to establish a *prima facie* case of same-invention double patenting and request that the rejection under 35 U.S.C. §101 be withdrawn.

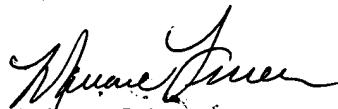
### **Fees Payable**

The addition of new claim 32, with the cancellation of claims 29-30 herein, does not increase the number of total claims beyond the number for which payment was previously made. Nevertheless, if any fee or charge is deemed properly payable in connection with the entry of this Amendment, the United States Patent and Trademark Office is hereby authorized to charge any payment necessary to the entry of this Amendment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

### **Conclusion**

The pending claims, as now amended, patentably distinguish over the prior art, and in view of the forgoing remarks, it is respectfully requested that all rejections be withdrawn thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Myers is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,



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